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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,711	07/28/2003	Shuwei Yang	51236US	7101
23911	7590	11/26/2004	EXAMINER	
CROWELL & MORING LLP INTELLECTUAL PROPERTY GROUP P.O. BOX 14300 WASHINGTON, DC 20044-4300			LEFFERS JR, GERALD G	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/627,711

Applicant(s)

YANG, SHUWEI

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2004.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-35 are pending in the instant application and are subject to the following restriction requirement.

#### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24 are drawn to methods for transferring a nucleic acid fragment of interest from Parent Molecule 1 to Parent Molecule 2 featuring the use of joinable ends (e.g. ligatable ends) and/or site-specific recombination reactions (e.g. Cre/LoxP), classified in class 435, subclass 91.1.
- II. Claims 25-34 are drawn to a PCR-based method for amplifying a nucleic acid fragment of interest, classified in class 435, subclass 91.2.
- III. Claim 35, drawn to a kit comprising Parent Molecule 1 and Parent Molecule 2, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Group I and Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I and II are biologically and functionally different and distinct from one another and do not render the other invention obvious. For example, the methods of Groups I and II comprise methods steps that are not required for or present in the methods of the other group: contacting a Parent Molecule 1 with a Parent Molecule 2 and using

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end-to-end ligation and/or site-specific recombination to generate an intermediate product (Group I) and contacting a target nucleic acid with first and second nucleic acid primers (Group II). The end results of the different methods are different: transfer of a desired nucleic acid fragment from one parent molecule to a second parent molecule (Group I) and PCR-mediated amplification of a target nucleic acid (Group II).

The invention of Group III and Groups I-II are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the parent molecules of the kit of Group III can be used in either of the patentably distinct methods of Groups I-II. For example, the parent molecule of Group III can be used as a source of the target nucleic for PCR amplification so long as the parent molecule comprises the target nucleic acid sequence of interest. Alternatively, the parent nucleic acid molecules could be used in any conventional cloning methodology not encompassed by the claims of Group I or Group II.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification. Further, the search required for Group I is not coextensive with that required for Group II. For example, the search of Group I requires a search for all site-specific recombinase mediated recombination/cloning methods, which is not required for the PCR-based methods of Group II. Further, the specific oligomers of Group II that are used as PCR primers are not recited in or necessarily required for the methods of Group I.

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Therefore, for each of these reasons given above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

### *Conclusion*


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

ggl

  
GERRY LEFFERS  
PRIMARY EXAMINER